State of Standardization in Central Densitometry

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Calibration

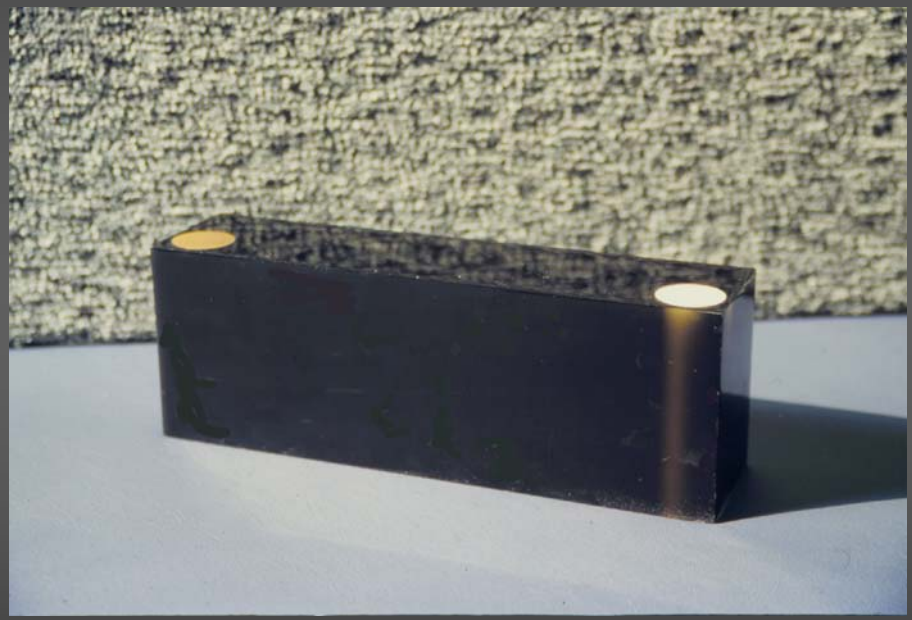
Feed back results into scanner

internal standard

Calibration

- Factory calibration
- On-site calibration
  - Service
  - Installation
- Daily calibration

Calibration Phantoms



Quality Assurance (QA)

Task: detect malfunction

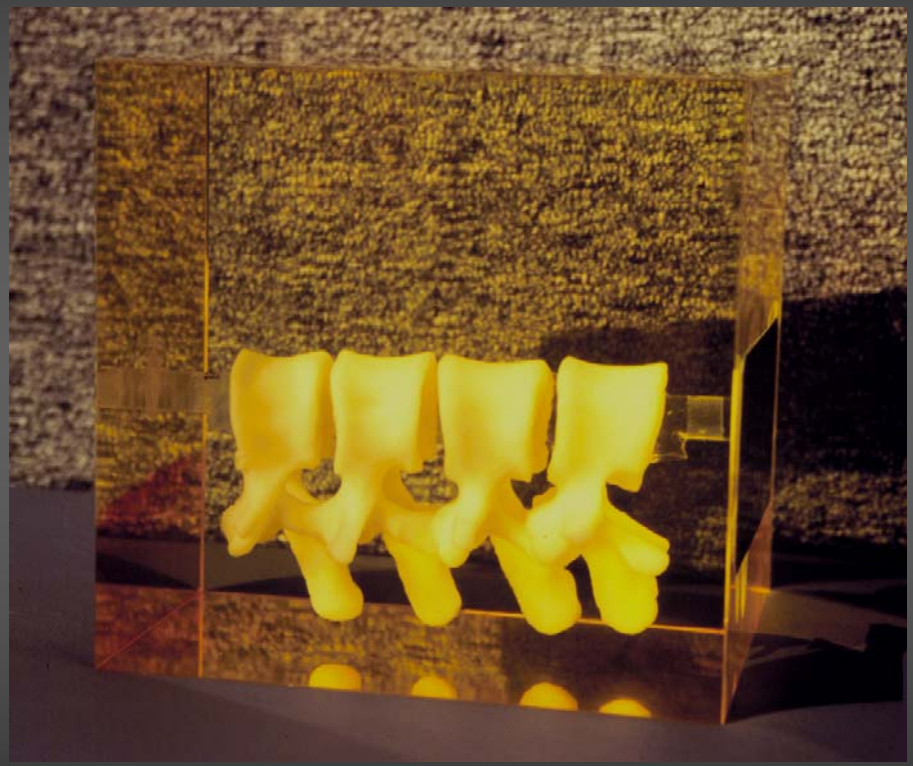
Action: repair

Quality Control (QC)

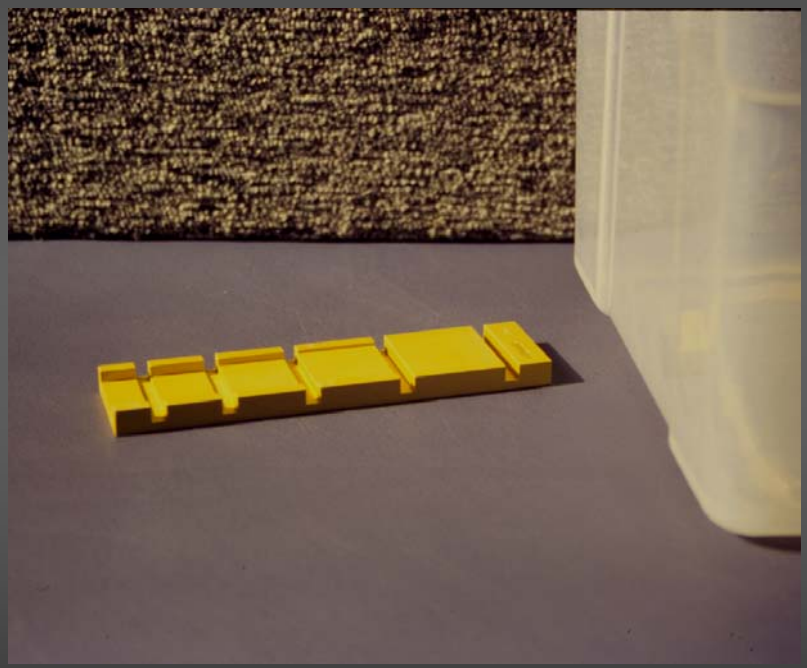
Task: retrospective assessment of scanner performance

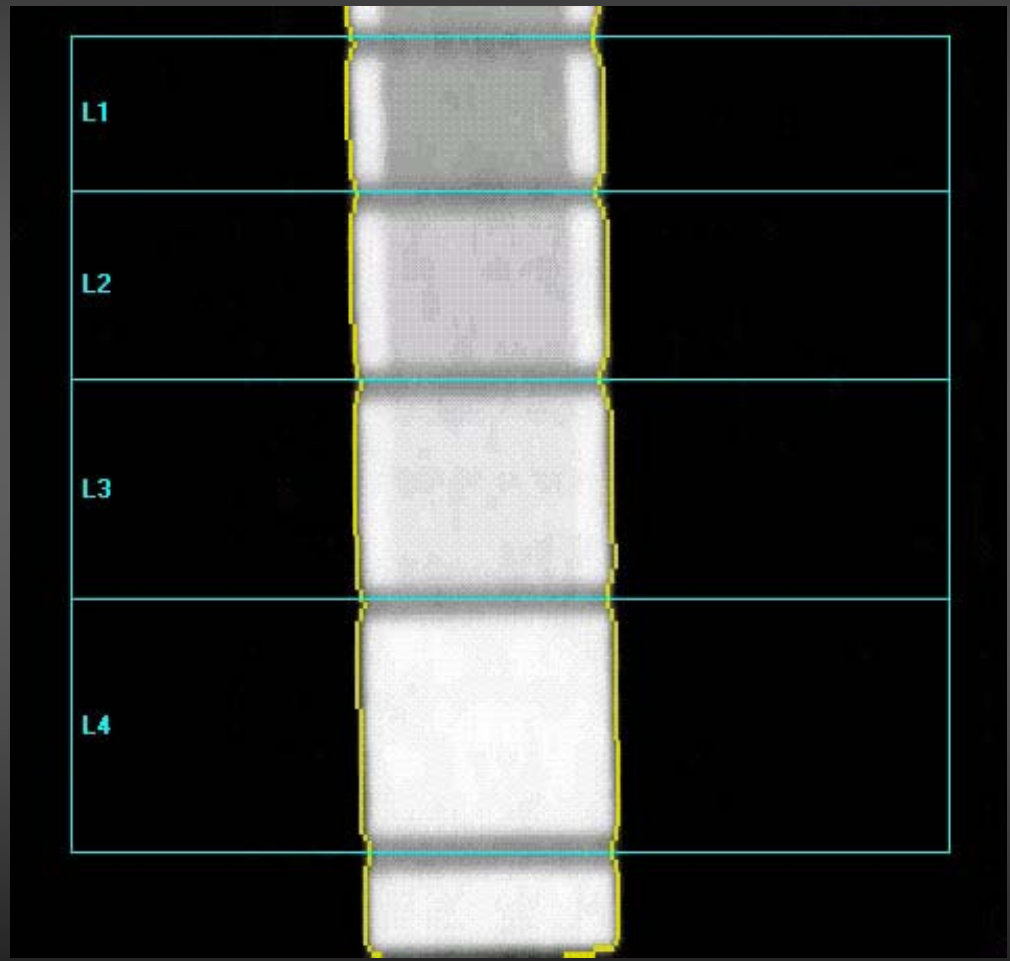
Action: calculate corrections

Hologic Spine Phantom



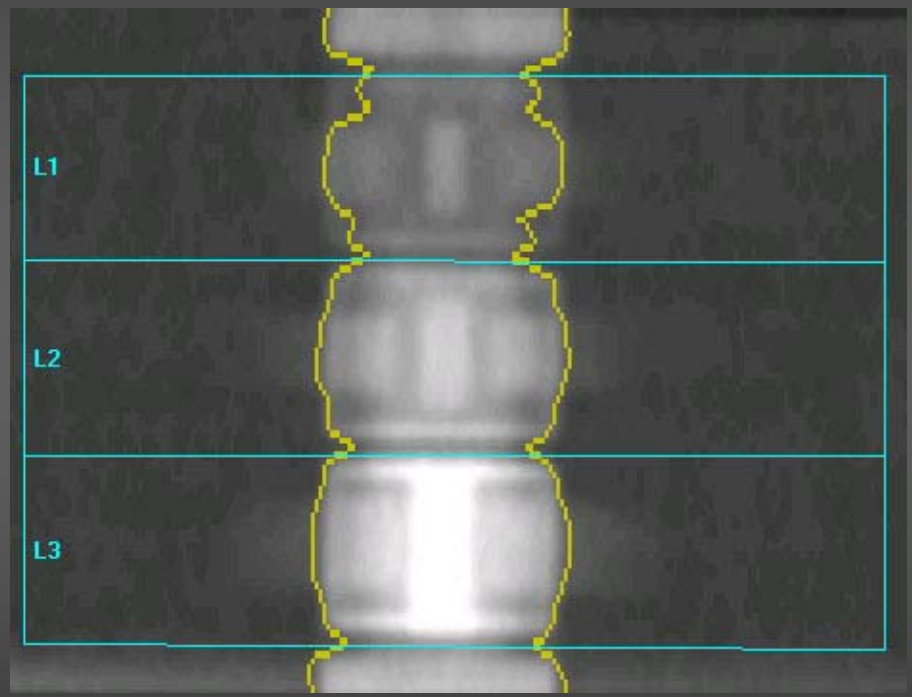
Lunar Step Wedge



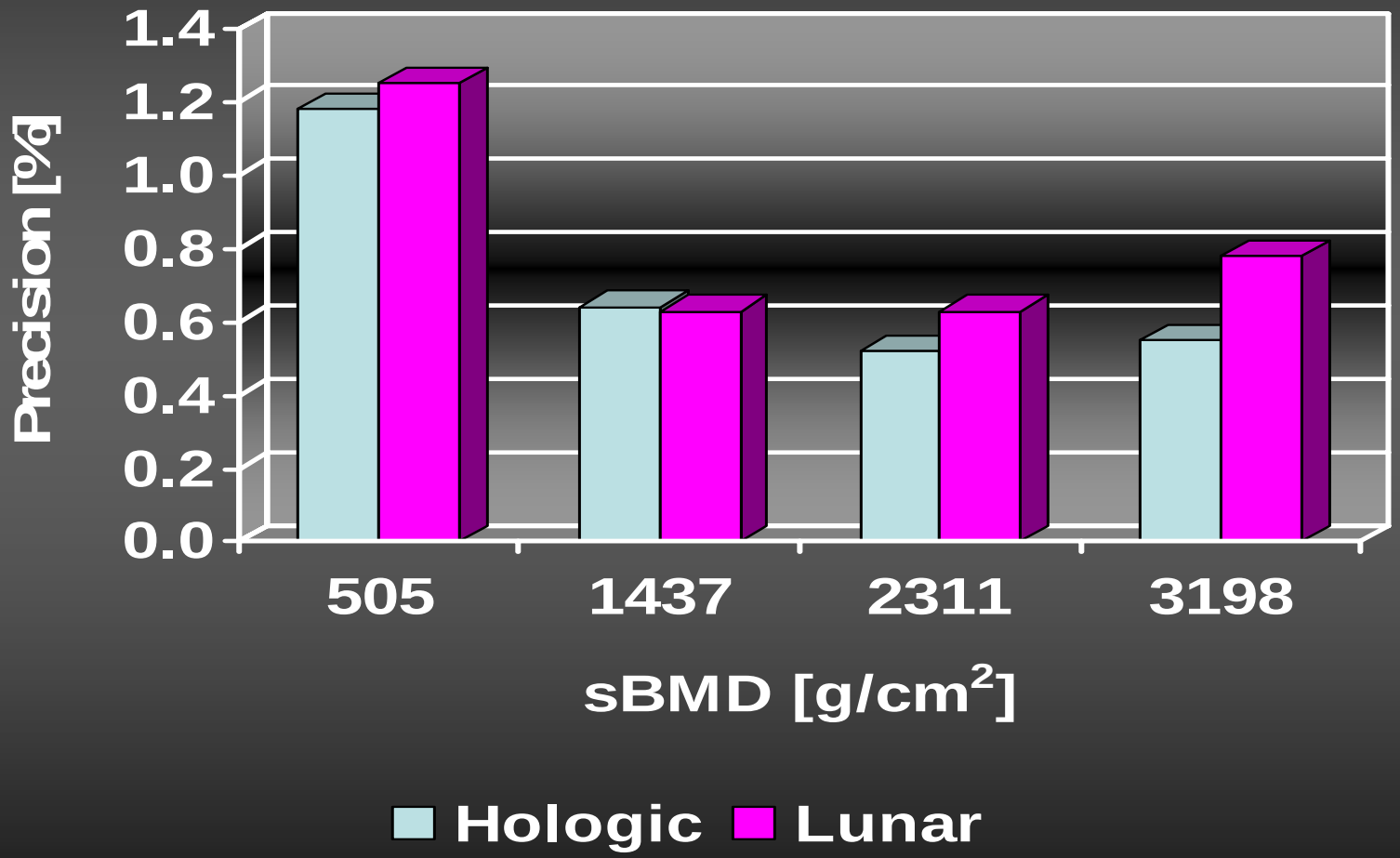


Bona Fide Step Wedge

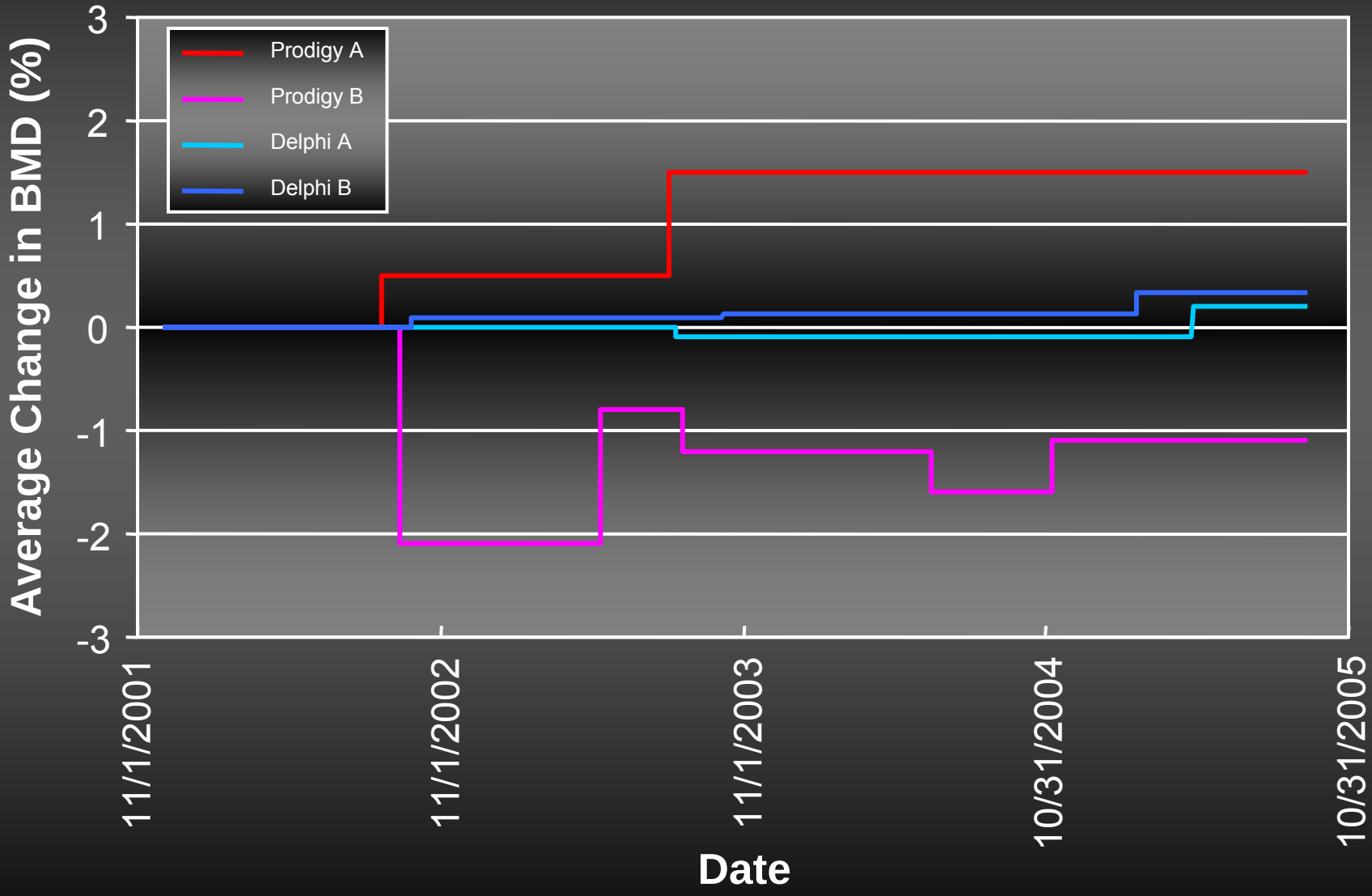
European Spine Phantom



Short-Term Precision



Long-Term Stability



Issues

- Different manufacturers
- Different models of same manufacturer
- Different scanners of same model
- Scanner service history
- Scanner operators

Different Models of Same Manufacturer (spine scanners)

Hologic

- QDR-1000 (pencil beam)
- QDR-4000 (pencil beam)
- QDR-4500 (transaxial fan beam)
- Delphi QDR (transaxial fan beam)
- Discovery QDR (transaxial fan beam)

Norland

- XR-26 (pencil beam)
- XR-36 (pencil beam)
- Eclipse (pencil beam)
- Excell (pencil beam)
- XR-46 (pencil beam)

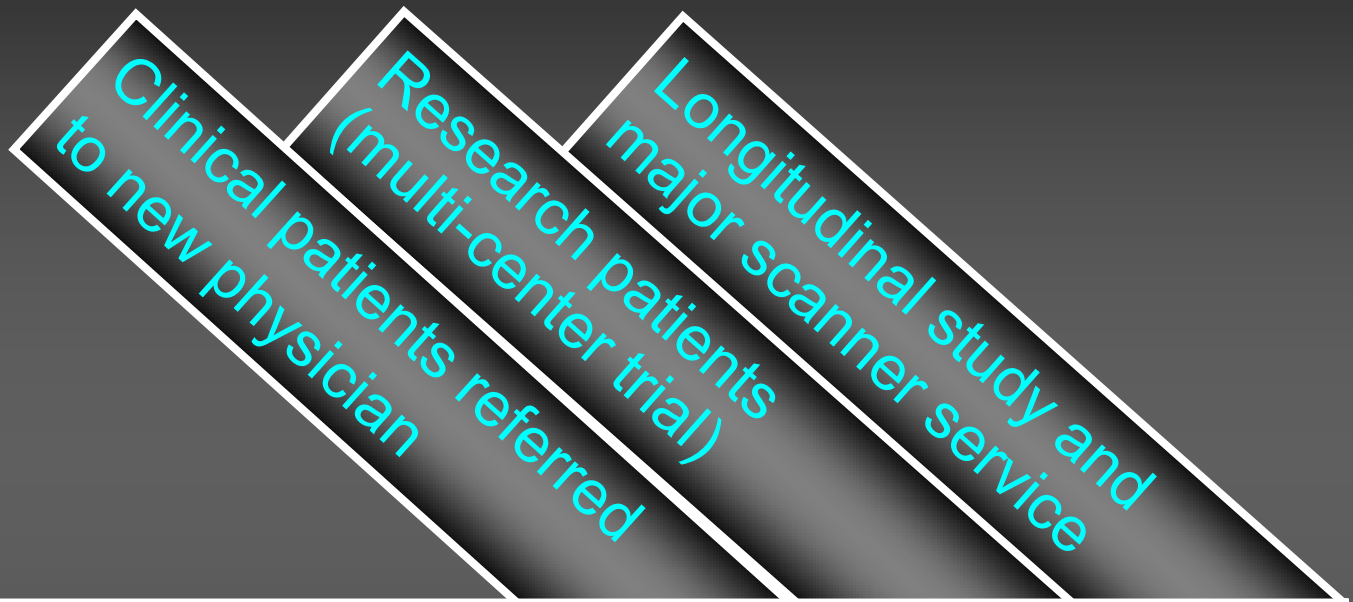
GE Lunar

- DPX-L (pencil beam)
- DPX-IQ (pencil beam)
- DPX Pro (pencil beam)
- Expert (cone beam)
- Prodigy (longitudinal fan beam)
- DPX Duo (longitudinal fan beam)
- iDXA (longitudinal fan beam)

DMS

- Challenger (pencil beam)
- Chronos (pencil beam)
- Lexxos (cone beam)

Need for Comparisons



	Clinical patients referred to new physician	Research patients (multi-center trial)	Longitudinal study and major scanner service
Manufacturer	✓	(✓)	
Model	✓	(✓)	
Different scanner of same model	✓	✓	✓

Standardization of DXA Values

Manufacturer

- GE Lunar
- Hologic
- Norland
- DMS

Site

- Spine A/P
- Spine lateral
- Femur
- Forearm
- Total Body

Parameter

- BMD
- BMC
- Area

Standardization Approach

Variables

- Density
- Region of Interest (edge detection)

Tools

- Phantoms (easy to repeat for new scanners)
- Patients (accurately reflect clinical situation)

Standardization Studies

Study Design

- Patients (plus European Spine Phantom for Spine Study)
- One scanner each from GE Lunar, Hologic and Norland

References

Spine: Genant HK et al., 1994, J Bone Miner Res 9:1503-1514
Hui SL et al., 1997, J Bone Miner Res 12:1463-1470
Femur: Hanson J, 1997, J Bone Miner Res 12:1316-1317
Lu Y et al., 2001, Osteoporos Int 12:438-444
Forearm: Shepherd JA, 2002, J Bone Miner Res 17:734-745

Standardization Equation

First Publication: only multiplicative relationship.

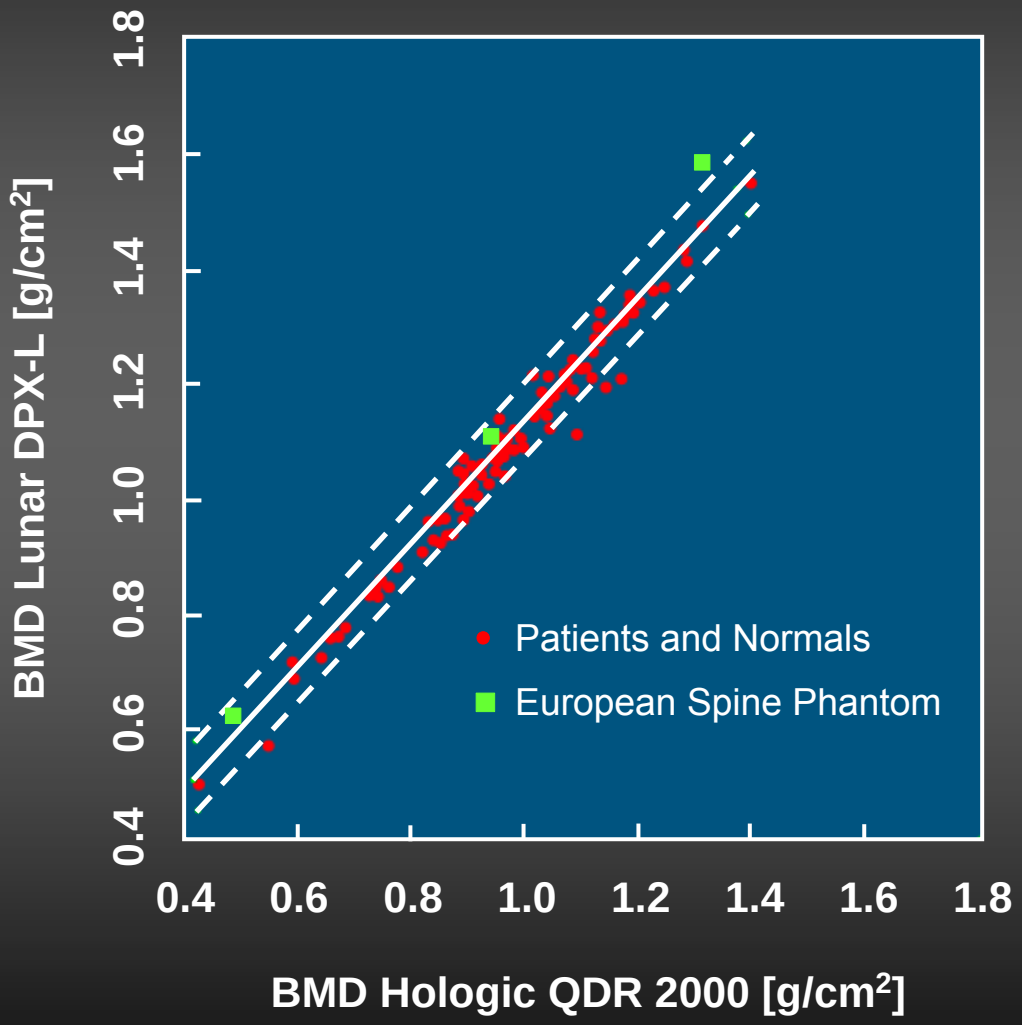
Example Hologic:

sBMD = 1.0755 BMD

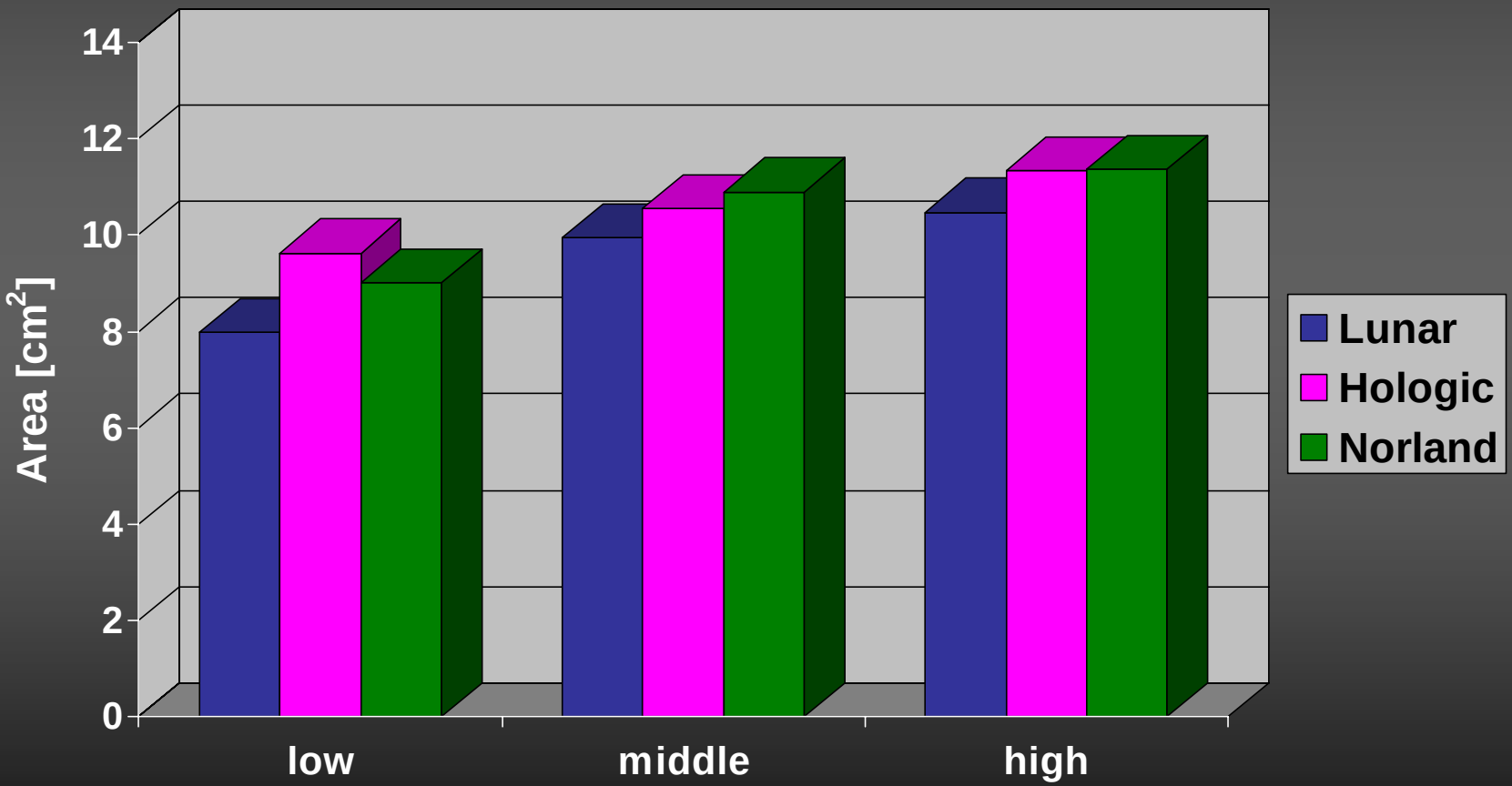
Improvement by Siu Hui, Ph.D.

sBMD = 1.0546 BMD+0.0182

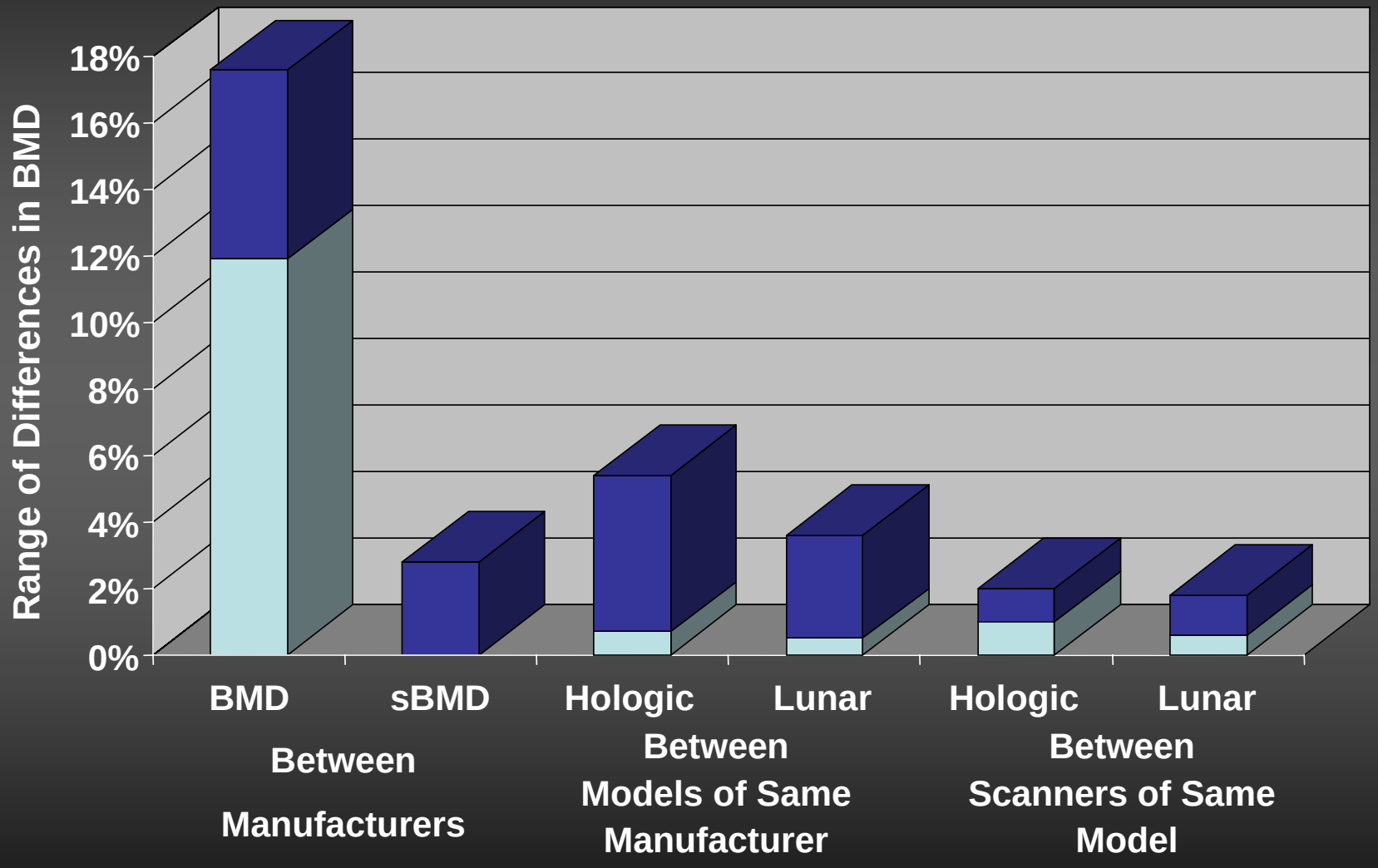
Standardization for Spine



Area of European Spine Phantom

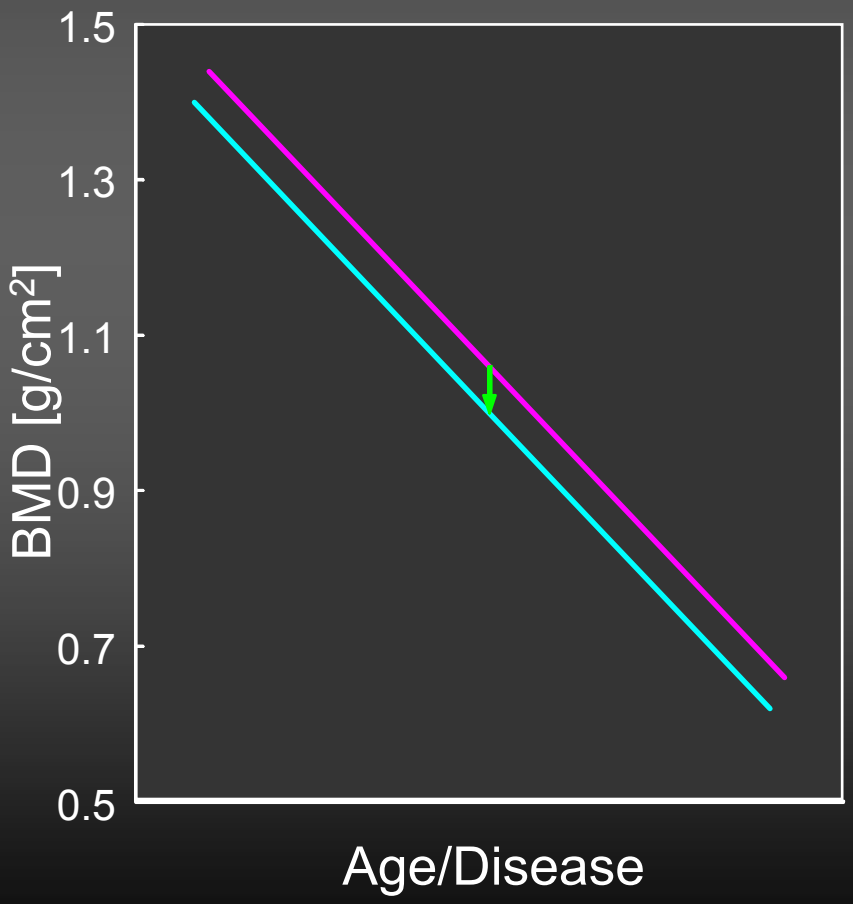


Summary of Differences

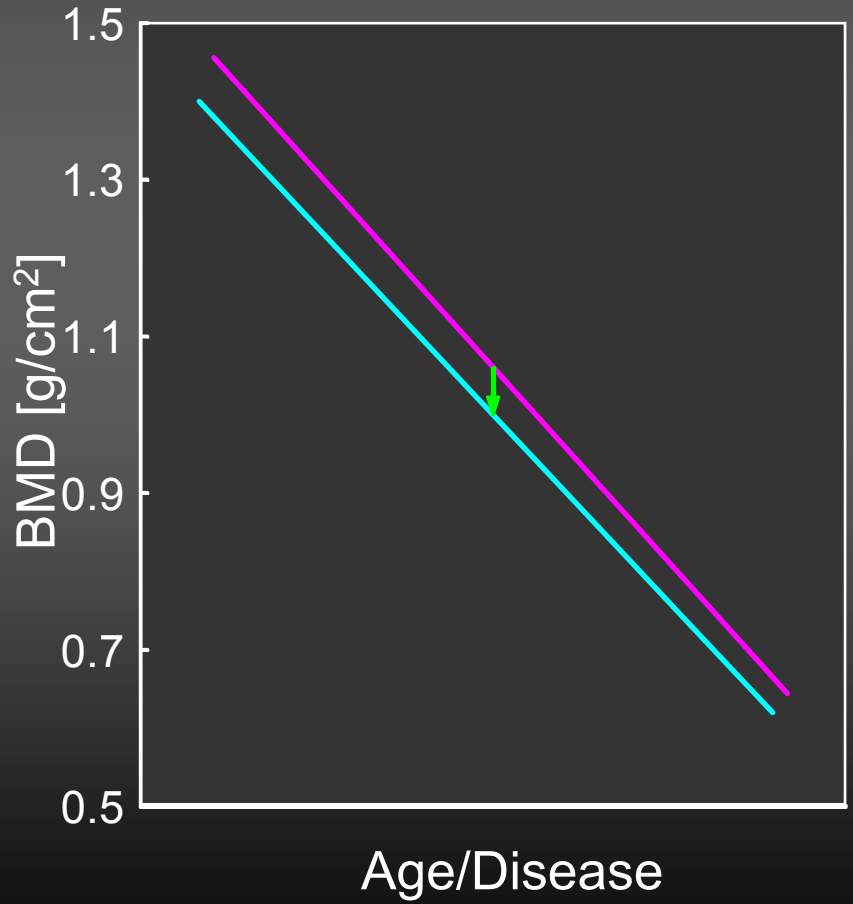


Density Values
"Shift the Same Way"

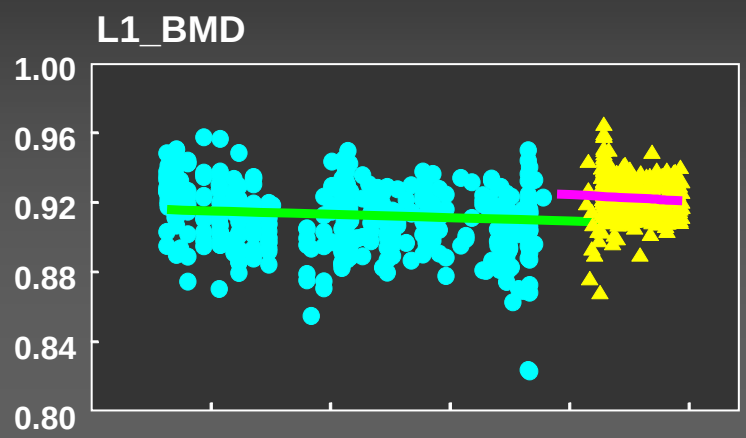
Additive

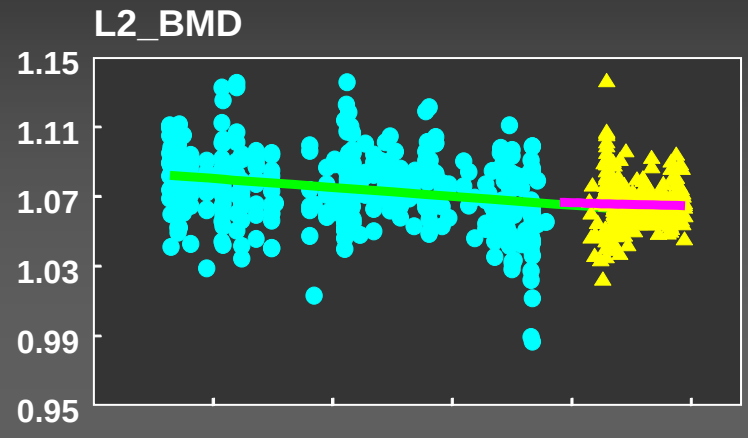


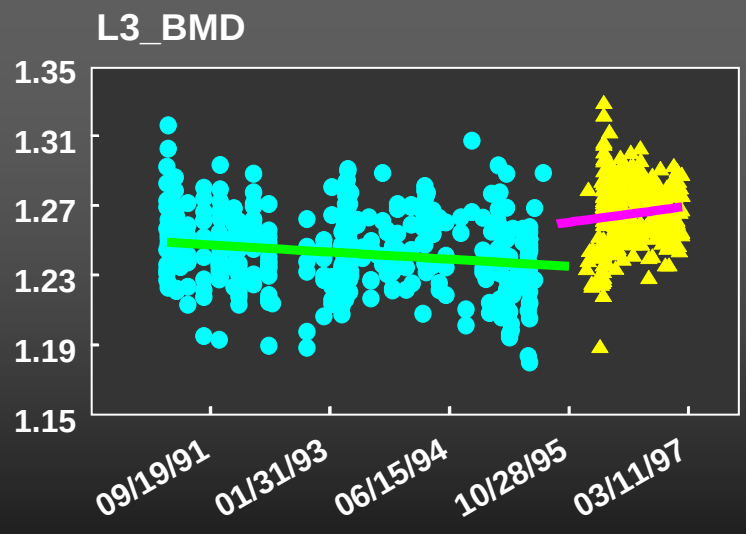
Multiplicative

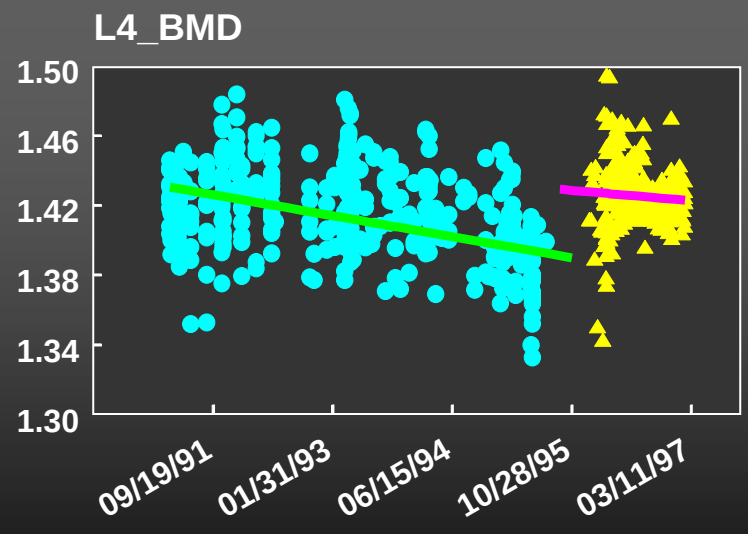


Lunar Step Wedge



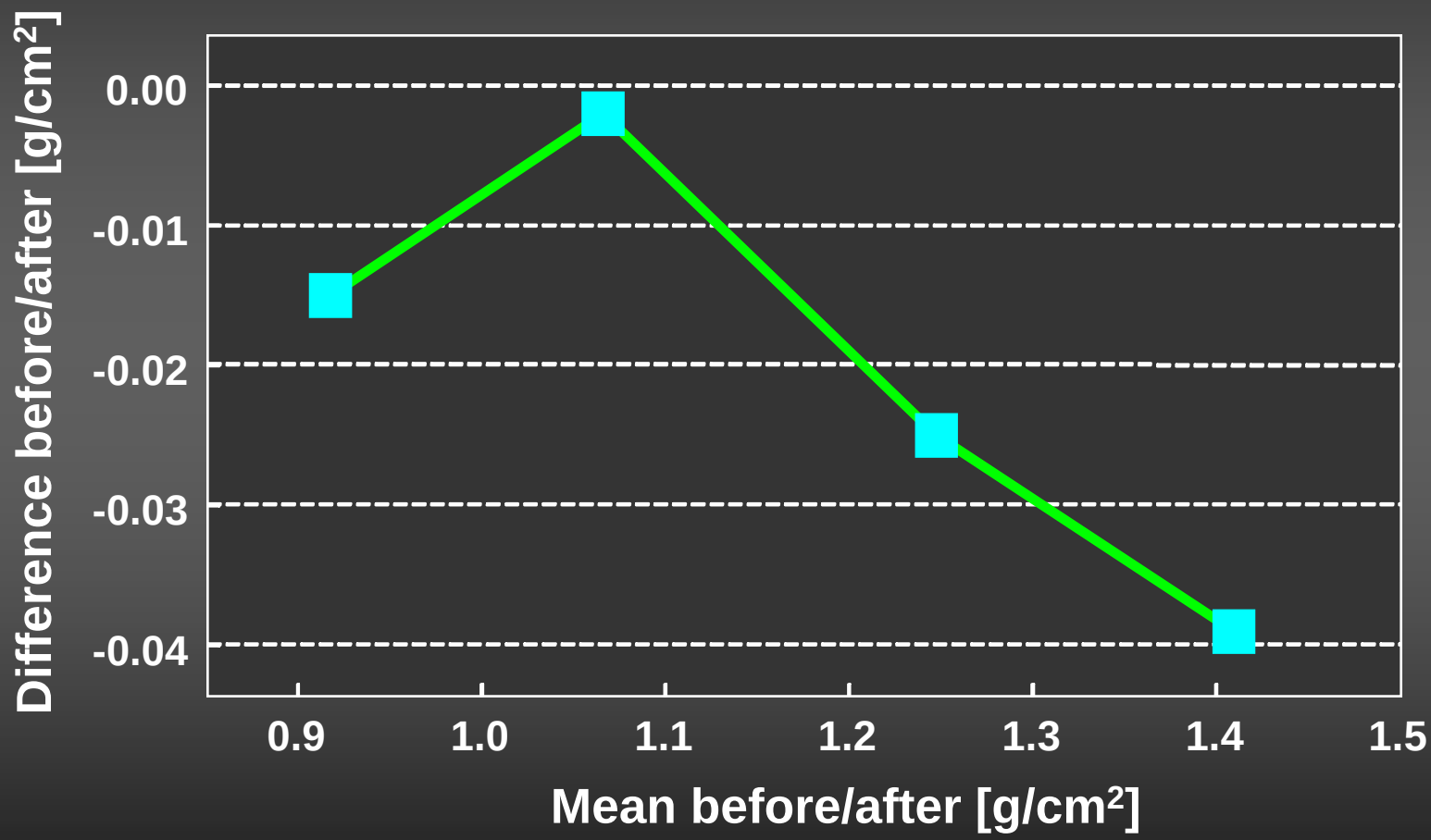




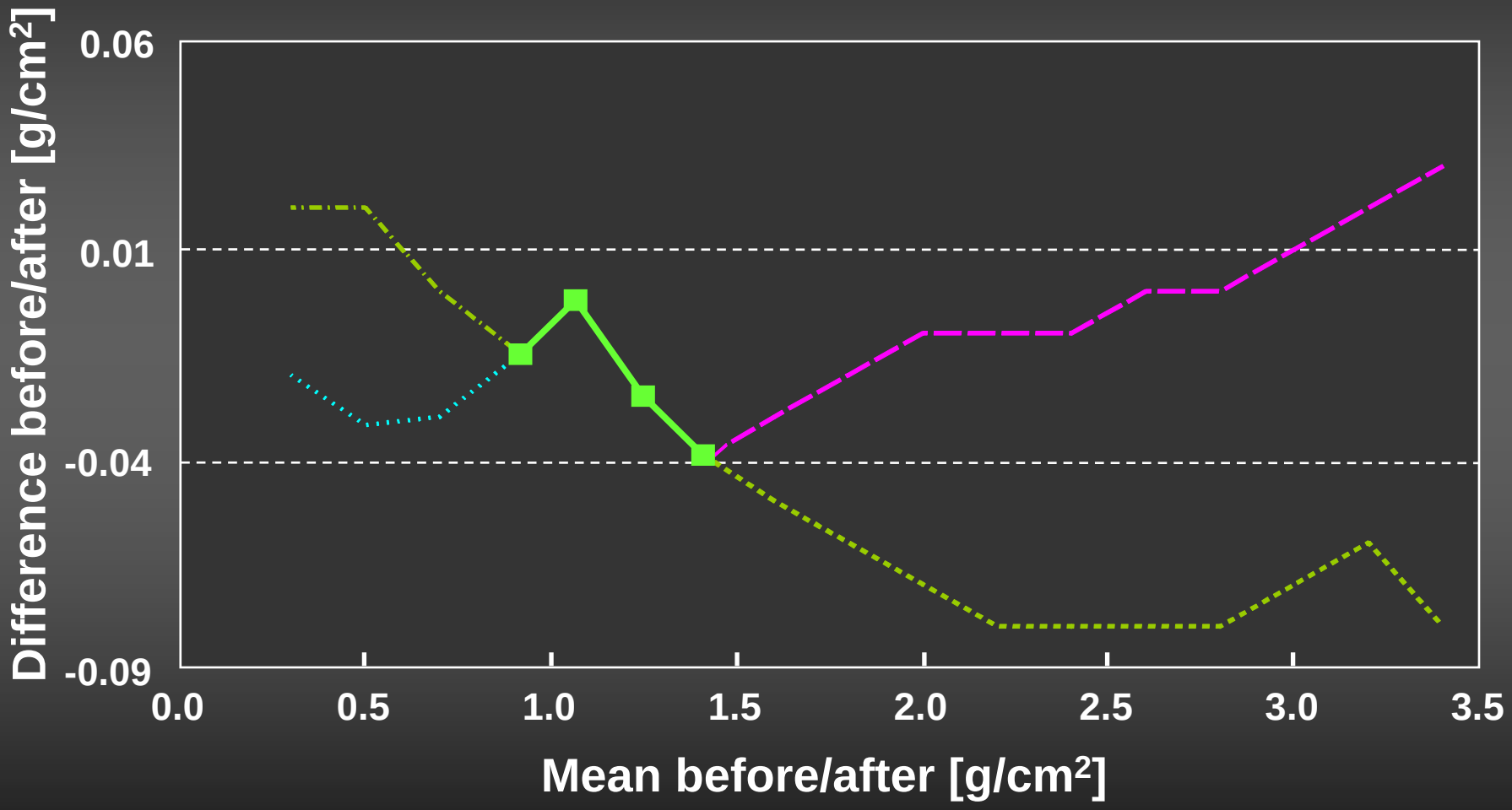


Lunar Step Wedge

BMD Analysis



Density-Dependent Changes

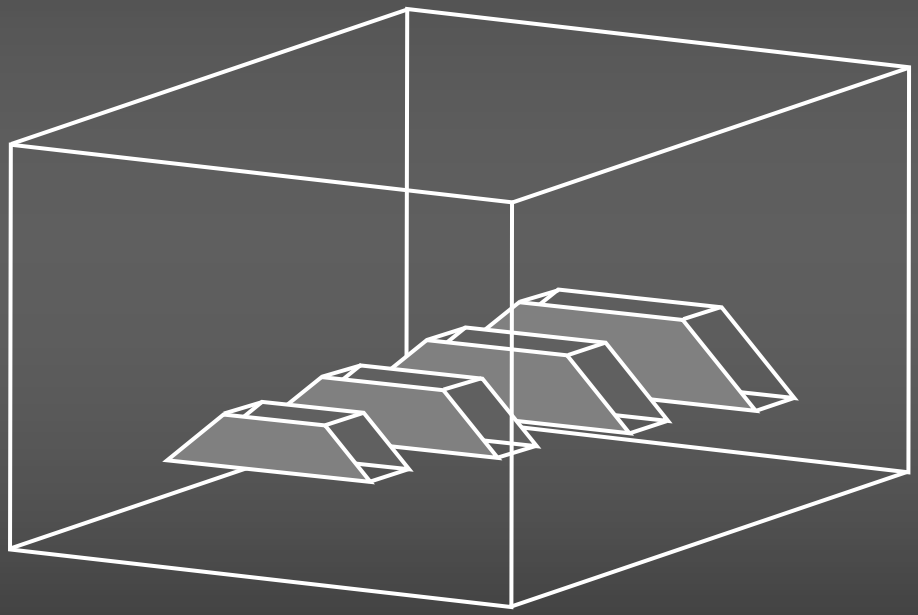


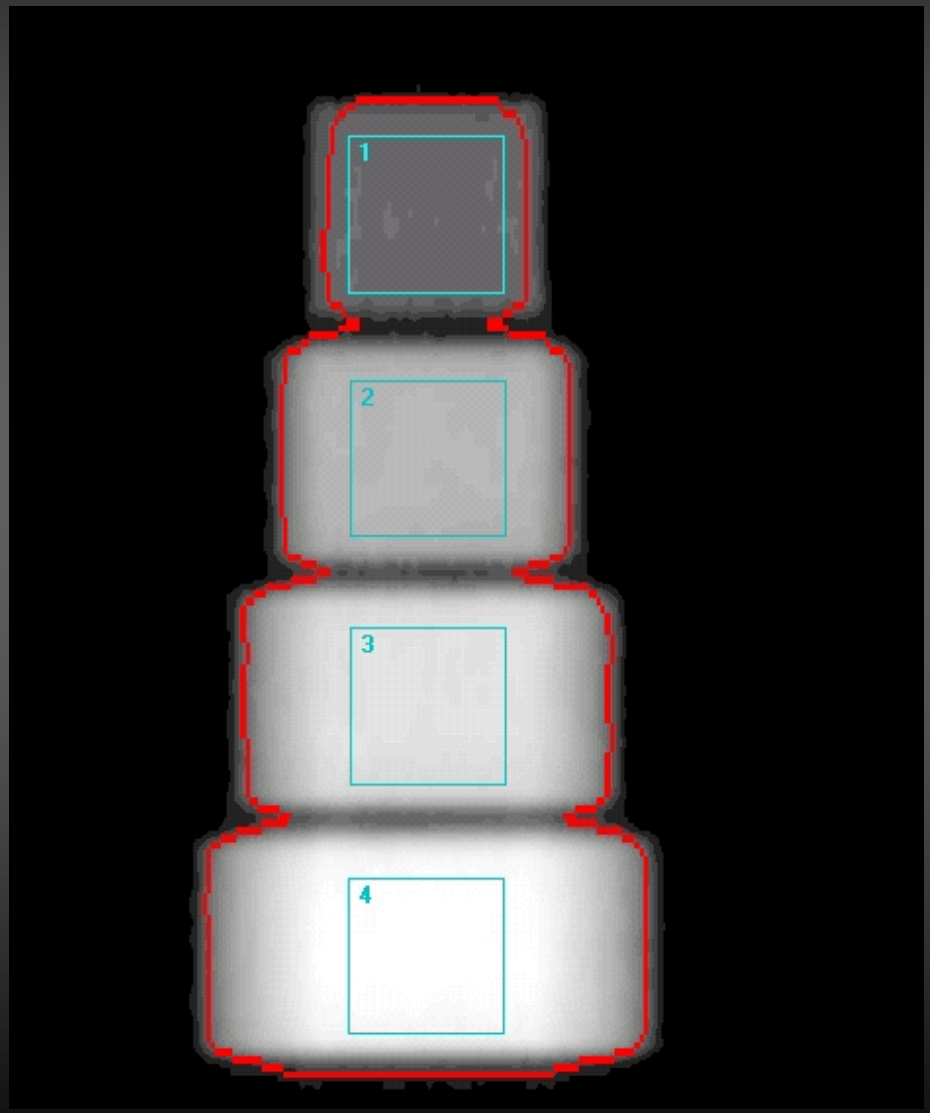
Properties of Phantoms

	Number of Density Values	Range of Density Values*	Testing of Edge Detection	Edge-Independent Density
Hologic Spine	1	1.1 – 1.2	✓	
Lunar Step Wedge	4	0.9 – 1.4		✓
Bona Fide Phantom	4	0.5 – 1.5		✓
European Spine Ph.	3	0.6 – 1.6	✓	
Hologic Block Ph.	3	0.7 – 1.8		✓
BMIL QA/QC Ph.	4	0.4 – 3.1	✓	✓
Human Spine		0.4 – 2.7		
Human femur		0.3 – 3.1		

*Lunar values

BMIL QA/QC Phantom





Requirements of Cross-Calibration

- Density range of clinical data
- Edge-independent BMD analysis
- Apply point-by-point correction (or histogram-dependent correction) unless proven that all density values “shift the same way”

Problem → Solution

Comparability for follow-up measurements

- on same scanner → tight limits on service
- on scanners of same manufacturer/technology → tight limits on service
- on scanners of different manufacturers/technologies →
  - standardization of ROI
  - full-range characterization of BMD
  - histogram-based translation of BMD

Barrier for Comparability of BMD between Manufacturers/Technologies

R&D?

Production?

Marketing?

End Use?

Steps to Achieve Comparability

- Agree on ROIs
  - issue: edge detection
    - » threshold
    - » gradient
- Modify analysis software
- Modify reference databases
- Develop software for histogram-based translation
- Run pilot trial with phantoms/patients
- Run larger trial with patients

Significance of Proposed Approach

- Expected lower error in comparability
- No further patient-based studies needed to establish correction/translation equations
    - Savings in cost
    - Savings in radiation dose to patients
- Correction/translation equations are based on individual scanners not models
- One set of phantom measurements sufficient to establish correction/translation equations for all measurement sites

Potential Providers of Solutions

- Cooperation necessary between manufacturers on
  - agreement on ROIs
  - agreement on edge detection
    - → additional studies needed to assess pros/cons of various edge detection approaches
      - » sensitivity to bone size (BMD)
      - » sensitivity to scanner drift (self correction?)
- Manufacturers need to create necessary software for
  - edge detection
  - histogram-based translation/correction
- Pilot study and larger trial could be run by
  - university-based research labs with experience in clinical trials and appropriate physics support
  - contract research organizations

Role for NIST

- Facilitate cooperation between manufacturers
- Help cover some of the costs for the trials
- Possible intermediary with other interested government agencies